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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,270	11/08/2001	Gregory S. Hageman	020618-000120US	3566

20350 7590 03/08/2004

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EXAMINER	
SEHARASEYON, JEGATHEESAN	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/007,270	HAGEMAN ET AL.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,10 and 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,10 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner J. Seharaseyon of Art Unit 1647.

2. This office action is response to Applicant's election of group I, claims 1-5 and 10-12 are drawn to nucleic acids of SEQ ID NO: 1. Election was made with traverse in the response filed 12/22/03. However, Applicant has traversed the requirement for sequence election. This is acknowledged. The traversal is on the grounds that there will be no hardship to the Office in performing a search with respect to the nucleotide sequences of SEQ ID Nos: 1, 3, 5 and 27, because it is argued that these sequences are isoforms or variants of the IPM 150. This is not found persuasive because as indicated in page 10 of the specification though the sequences have substantial identity they nevertheless encode proteins of different length. Therefore, IPM 150 proteins (isoforms or variants) containing these sequences are structurally and functionally different. Thus, the searches for each of the different sequences are not coextensive and would be a burden on the office to search all of the different sequences. Therefore, IPM 150 comprising SEQ ID NO: 1 encoding the protein of SEQ ID NO: 2 will be searched. The requirement is still deemed proper and is therefore made FINAL. Applicant has elected to cancel claims 6-9 and 12-20. Therefore claims 1-5, 10 and 11.

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Priority

4. Applicant is required to update the priority information in the first paragraph of the application with the current status of all applications to which reference is made.

Claim Objections

5. Claims 1-5 are objected to because of the following informalities: The claims also recite unelected inventions. The claims need to be rewritten reciting only the elected inventions. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 10-11are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6a. Claim 1 recites " wherein said nucleotide sequence hybridizes under stringent conditions to .....", is vague and renders the claim indefinite. "Stringent conditions" is relative term and thus the metes and bounds of the claim, cannot be ascertained. This rejection could be obviated by providing specific conditions supported by the specification that Applicants consider be "stringent." Claims 10 and 11 are rejected insofar as they depend on rejected claim 1.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5, 10 and 11 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 1-5, 10 and 11 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific substantial and credible utility. The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose the biological role of the nucleic acid, the encoded protein or the significance of either.

It is clear from the instant specification that the "IPM 150" (interphotoreceptor matrix) protein encoded by SEQ ID NO: 1 described therein is what is termed an "orphan protein" in the art. This is a protein whose cDNA has been isolated because of its similarity to known proteins. There is little doubt that, after complete characterization, this protein, and the nucleic acid encoding it, may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its

broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claims are drawn to nucleotides encoding a protein of as yet undetermined function or biological significance. Applicant asserts that the discovery of novel IPM components allows identification of novel therapeutic and diagnostic agents for diseases or condition associated with abnormal IPM, such as retinal detachment, chorioretinal degenerations, retinal degenerations and macular degenerations such as AMD, or other dystrophies or degenerations involving IPM, cone or rod (paragraphs 24). However, there is absolutely no evidence of record or any line of reasoning that would support a conclusion that the "IPM 150" protein of the instant application could be used in a methods of diagnosis, treatment, amelioration and/or prevention of diseases, disorders and conditions associated with IPM 150 polypeptides (paragraphs 24 and 89 of the specification). Applicant suggests that IPM 150 polypeptides may be useful in diagnosing or treating diseases and conditions affecting eye (paragraph 24 and 89) and also play a role in maintaining photoreceptor cell viability (paragraph 79). Thus, it is

claimed that IPM 150 may be useful in the diagnosis and treatment of diseases such as retinal detachment, chorioretinal degenerations, retinal degenerations and macular degenerations such as AMD, or other dystrophies or degenerations involving IPM, cone or rod (paragraphs 24). Neither the specification nor the prior art demonstrates a causal correlation or nexus of the claimed polypeptide with any of the conditions or disorders contemplated by the instant specification, therefore, there is no evidence of record that would provide for a method of treating/diagnosing any of the listed conditions or disorders. Accordingly, the skilled artisan would not consider such assertions to be substantial. There is absolutely no evidence of record or any line of reasoning that would support a conclusion that the "IPM 150" protein of the instant application is involved in retinal adhesion through interaction with hyaluronan. The record fails to indicate any evidence of any of these biological activities, and it would appear that until some actual and specific significance can be attributed to the protein identified in the specification as IPM 150, the gene encoding it, or the antibody that binds it, the instant invention is incomplete. The specification asserts that the claimed protein will have activities similar to other IPM proteins based on amino acid sequence similarity (paragraphs 42), but it is not clear or predictive which activity of the IPM family will be possessed by the claimed protein based on structural similarity alone.

The protein of the instant specification is known to contain glycosylation consensus sequences, cluster of cysteine residues, EGF-like domain and potential hyaluronan binding motifs (paragraph 77). It is asserted that IPM 150 may play a role in retinal adhesion through interaction with hyaluronan. Therefore, it does not appear that the

Applicant knew the biological significance of IPM 150 at the time of filing. In the absence of knowledge of the biological significance of "IPM 150", there is no immediately available patentable use for it. Furthermore, the prior art of record demonstrates that the biological function of the protein family to which the disclosed protein is said to be a member is so diverse, that one could not predict which biological activity is possessed by the disclosed protein based on structural similarity alone, especially since all the members share structural similarity, but not functional similarity. To employ the instant invention in any of the disclosed methods would clearly be using it as the object of further research that has been determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for the claimed invention, it is incomplete and, therefore, does not meet the requirements of 35 U.S.C. §101 as being useful.

It is noted in the specification, that it in addition to the retina IPM 150 message is also found in human adult and fetal lung and thymus, as well as to adult kidney and small intestine (paragraph 82). In addition, ESTs partially homologous to the IPM 150 cDNA sequence have been identified from human endothelial cell and brain cDNA libraries (paragraph 82). However, these disclosed properties of the claimed protein, expression pattern and potential therapeutic uses do not provide a specific, substantial and credible utility for the claimed polypeptides because there is no nexus between the expression and the diseases. The instant specification fails to teach that the claimed polypeptide is diagnostic for any specific disease. In addition, there is no correlation of the expression between normal and disease tissues. In fact, Applicants' own work

states that "Knowledge of IPM 150 cDNA sequence will enable us to develop specific probes directed against it and to generate transgenic animal models to more closely examine the function of this unique proteoglycan *in vivo*. Together, these experiments should provide additional insight into the role of the IPM in the normal and diseased human retina as well as in non-retinal tissues that express IPM150" (Kuehn et al., page 517). Since neither the prior art nor the specification provides for the physiological significance of the disclosed and claimed receptor, there is no immediately obvious patentable use for it.

In addition, the instant specification does not disclose a "real-world" use for said polypeptides and polynucleotides, except the prophetic recitation of potential uses, which include possible biological and therapeutic uses. Also, there are no working examples that demonstrate any specific utility. Thus, the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. 101 as being useful. Therefore, since the peptide of the invention is not supported by a specific and substantial asserted utility or a well established utility, then the composition comprising the polypeptide and a carrier also are not supported by a specific and substantial asserted utility or a well established utility.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 and 10-11 are rejected under 35 U.S.C. §112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above in paragraph 7, with regard to the rejection of these claims under 35 U.S.C. §101.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9a. Claims 1-3 and 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonaldo et al. (1996).

The instant invention is directed to nucleotide sequence, that hybridizes to at least 540 contiguous nucleotide residues of SEQ ID NO: 1 or comprises at least 540 contiguous nucleotide residues of SEQ ID NO: 1.

Bonaldo et al. (1996) describes a cDNA sequence which has 100% identity from nucleotide 2787 to 3330 (see Appendix A). Therefore, the disclosure of Bonaldo et al. (1996) et al. anticipates claims 1-3 and 10-11.

10. No claims are allowable.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kuehn et al (1999) Matrix Biol. 18(5), pages 509-518. Kuehn et al. discloses the nucleotide of SEQ ID NO: 1 and polypeptide of SEQ ID NO: 2. However, this is the Applicants' own work and was published after the earliest priority date.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JS

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER